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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/716,619

11/20/2003

John P. Daley

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26111

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06/28/2006

STERNE, KESSLER, GOLDSTEIN & FOX PLLC
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WASHINGTON, DC 20005

EXAMINER

SHUKLA, RAM R

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 06/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/716,619	Applicant(s) DALEY ET AL.	
	Examiner Malou C. Gemeniano	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/17/04.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 55-75 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- 55-58 65 and 75*
- I. Claims ~~56-58~~ and ~~65~~-68, drawn to serum free eukaryotic cell culture wherein ingredients support the expansion of CD34+ hematopoietic cells, classified in class 435, subclass 405.
- 63*
- II. Claims 59-60, 62-~~59~~, 72-73 and 69-71 drawn to a method of expanding CD34+ hematopoietic cells in culture, classified in class 435, subclass 325.
- III. Claims 61, 64, 70 and 74, drawn to method of providing recombinant CD34+ hematopoietic cells to mammals, classified in class 424, subclass 93.1 .

Claims 55 and 65 are linking claims that link(s) inventions I-III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 55 and 65. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the

continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Group I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, group I is drawn to serum free eukaryotic cell culture wherein ingredients support the expansion of CD34+ hematopoietic cells and group II is drawn to a method of expanding CD34+ hematopoietic cells in culture. The product, the serum free medium can be used to expand other types of cells or cell line especially when it contains the minimum ingredients to grow other mammalian cells lines. In addition, Group I and II inventions have different status of the art as well as divergent classifications. The search for product claimed would not overlap with the method to expand CD34+ hematopoietic cells; therefore, the two searches would not be co-extensive and would be a serious search burden on the Examiner. Because of reasons stated above, restriction as indicated is proper. Group I and Group II are classified differently under US Patent

Classification guidelines, to search them together would present a search burden on the examiner due to the extensive databases of non-patent literature. Because a search of one does not necessarily overlap with that of another species, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated.

Groups I and III are directed to patently distinct inventions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the product of Group I is drawn to serum free eukaryotic cell culture wherein ingredients support the expansion of CD34+ hematopoietic cells. The methods of Group III relate to providing recombinant CD34+ hematopoietic cells to mammals. Group I and III have different functions. For example, the product for Group 1 is important for the growth of CD34+ cells in culture in vitro. The serum-free medium of Group 1 is not necessarily utilized in the method of introducing CD34+ cells into mammals. The method of Group 2 contains steps and reagents that do not necessitate the same steps and reagents of Group 1. Because these inventions are distinct for the reasons given above the search required for invention 1 is not required for group 3, restriction for examination purposes as indicated is proper. Invention 1 and 3 are classified differently under US Patent Classification guidelines, to search them together would present a search burden on the examiner due to the extensive

databases of non-patent literature. Because these inventions are structurally distinct for reasons given above, and because a search of Group 1 does not necessarily overlap with that of Group III, the searches are not co-extensive, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated.

Groups II and III are directed to patently distinct inventions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Group II drawn to method of expanding CD34+ in vitro and Group III drawn to method of introducing CD34+ into mammals. Each method has a different mode of operation, different function and effect. The method of Group II involves expansion of CD34+ in tissue culture and therefore requires different steps and reagents while Group II involves introducing CD34+ into mammals. The steps and reagents in Group II are different from the steps and reagents needed in Group III. In this instant case, the search for each Group would not be co-extensive and the search of the method of Group II would not overlap with the search of the method of Group III; thus, a serious search burden would be placed on the Examiner. For example, the method of Group II is drawn to different starting materials as well as has different effects and objective than that from Group III. The scope of each group would not overlap with each other. Because of divergent search strategies and reasons stated above, restriction as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the response for this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Dianiece Jacobs, whose telephone number is (571)-272-0532.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malou C. Gemeniano whose telephone number is 571-272-6451. The examiner can normally be reached on 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

For all other customer support, please call the USPTO Call Center (UCC) at (800)-786-9199.

Malou C. Gemeniano, Ph.D
Examiner, USPTO, AU 1632



DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER